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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,169	07/27/2006	Kagayaki Kuroda	198812	7831

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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	**PAPER NUMBER**
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,169	KURODA, KAGAYAKI	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The Information Disclosure Statement submitted on January 10, 2006 is acknowledged. The Information Disclosure Statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-2, 5-8, 13-14, 17-20, 25-26, and 31-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Komura et al. (US Patent No. 6,566,878).

With regards to claim 1, Komura et al. disclose a method comprising the steps of: when a local temperature change takes place in a certain position inside an object, acquiring measured phase distribution image representing a temperature distribution inside said object using, as a temperature indicator, a phase of complex magnetic resonance signals from water photons inside said object observed by a magnetic resonance tomographic imaging technique (column 1, lines 22-67; column 4, lines 29-44); defining a certain position in said acquired measured phase distribution image as a region of interest (column 6, lines 47-63; referring to operator specifying ROI on a

temperature distribution screen); estimating a phase distribution of complex magnetic resonance signals before a temperature change in said region of interest based on a phase distribution of complex magnetic resonance signals in a portion surrounding said region of interest (column 2, lines 59-63; referring to getting a reference phase within the region where temperature is not changing; column 6, lines 47-66, referring to selection of reference points and spatial phase distribution calculation; column 7, lines 13-24, referring to the case in which position and size of a temperature change is predicted, and ROI is specified before imaging and reference point is selected by specifying this ROI; See Figure 6); acquiring an estimated phase distribution image based on said estimated phase distribution (column 7, lines 24-30); calculating an amount of phase variation of complex magnetic resonance signals caused by a temperature change in said region of interest by conducting subtraction between said measured phase distribution image and said estimated phase distribution image on a pixel-by-pixel basis (column 7, lines 30-36); and measuring an amount of a temperature change in said region of interest based on said amount of variation (column 1, lines 56-67; column 8, lines 52-54).

With regards to claim 2, Komura et al. disclose a method comprising the steps of: when a local temperature change takes place in a certain position inside an object, acquiring a real-part image and an imaginary-part image as measured complex images incorporating a temperature distribution inside said object using, as a temperature indicator, a phase of complex magnetic resonance signals from water protons inside said object observed by a magnetic resonance tomographic imaging technique (column

1, lines 43-67); defining the same position in said acquired real-part and imaginary-part images as a region of interest (column 6, lines 47-63; referring to operator selection of ROI); estimating a distribution of a real part and an imaginary part of complex magnetic resonance signals before a temperature change in said region of interest based on a distribution of a real part and an imaginary part of complex magnetic resonance signals in a portion surrounding said region of interest (column 2, lines 59-63; column 6, lines 47-66; column 7, lines 13-24; See Figure 6); acquiring an estimated complex image based on said estimated real-part and imaginary-part distribution (column 7, lines 24-30); calculating an amount of phase variation of complex magnetic resonance signals caused by a temperature change in said region of interest by calculating a phase difference between said measured complex image and said estimated complex image on a pixel-by-pixel basis (column 7, lines 30-36); and measuring an amount of temperature change in said region of interest based on said amount of variation (column 1, lines 56-67; column 8, lines 52-54).

With regards to claims 5-6 and 17-18, the method and system further comprises the step of conducting subtraction between a measured phase distribution image and an estimated phase distribution image on a pixel-by-pixel basis by multiplying complex conjugates of complex numbers of complex magnetic resonance signals with each other and calculating an arctangent of the product (column 1, lines 43-56).

With regards to claims 7,19, 25 and 31, the method of claim 1 further comprises the step of outputting a distribution image of the amount of temperature change based on the amount of phase variation of complex magnetic resonance signals superimposed

over an anatomical image of organ or tissue acquired by a magnetic resonance tomographic imaging technique (column 10, lines 10-14; See Figure 9).

With regards to claims 8, 20, 26, and 32, the method and system further comprises the means and step of capturing a phase distribution image of complex magnetic resonance signals in one, two or three orthogonal planes intersecting an extension of an in-body penetrating portion fo a heating or cooling apparatus during thermo treatment or cryo-treatment so as to include a tip of said in-body penetrating portion, or in two or more parallel planes (column 1, lines 13-26; also see Figures 8-9, wherein a catheter (i.e. heating or cooling treatment) is included in the image planes).

With regards to claims 13 and 14, Komura et al. disclose a magnetic resonance image diagnosing apparatus that includes a computer (208), an operating module (221) with a keyboard (222) and mouse (223), and a signal processing system (206) for carrying out their method as discussed above (column 3, line 50 through column 4, line 44; column 6, lines 1-23; see Figure 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3-4 and 15-16, are rejected under 35 U.S.C. 103(a) as being unpatentable over Komura et al. in view of Bernstein et al. (US Patent No. 5,226,418).

As discussed above, Komura et al. meet the limitations of claims 1-2 and 13-14. However, they do not specifically disclose that their method and apparatus further comprises the step of estimating a phase distribution of complex magnetic resonance signals (or a distribution of a real part and an imaginary part) in a region of interest by applying higher-order polynomial fitting by a linear least squares method, functional fitting by a non-linear least squares method, or a finite element method to a phase distribution of complex magnetic resonance signals in a portion surrounding said region of interest. Bernstein et al. disclose a method and apparatus for producing NMR angiograms using the image domain complex difference method and for reducing image artifacts in such angiograms due to system phase errors (column 4, lines 63-68). They further disclose that their method includes the step of performing phase corrections calculated from the image domain NMR data sets using a least squares fit (column 11, line 33 through column 12, line 61). They further disclose that the correction can easily be extended to orders higher than linear (column 12, lines 40-43). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have included the above step to the method of Komura et al. The motivation for doing so would have been that using a least squares method provides adequate suppression of regions of low signal, as taught by Bernstein et al. (column 11, line 64 through column 12, line 3).

7. Claims 9-10, 21-22, 27-28 and 33-34, are rejected under 35 U.S.C. 103(a) as being unpatentable over Komura et al. in view of Conlan et al. (US Patent No. 5,904,147).

With regards to claims 9-10, 21-22, 27-28 and 33-34, as discussed above, Komura et al. meet the limitations of claims 8, 20, 26 and 32. Further, as can be seen from Figure 8, the image includes the tip of a catheter. However, they do not specifically disclose that their system further comprises checking the position of the tip of the in-body penetrating portion of the heating or cooling apparatus using an optical positioning apparatus, nor do they disclose providing a marker at the tip of said in-body penetrating portion, and checking a position of the tip of said in-body penetrating portion by detecting said marker in an MRI image or numerically detecting it. Conlan et al. disclose a balloon-tipped catheter and to a method of use to control hemorrhage during surgery (column 1, lines 7-9). They disclose that a light fiber extends through the catheter body to emit a light that is relatively bright and allows the position of the balloon in the vessel to be directly and quickly determined (i.e. optical positioning) (column 3, lines 1-12). The light (i.e. marker) provided is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip (column 6, lines 36-39). At the time of the invention, it would have been obvious to use an optical positioning apparatus to check the position of the tip of the penetrating apparatus and provide a marker at the tip of said penetrating potion that is detectable in the MRI image. The motivation for doing so would have been to provide an improvement in speed and dependability in procedure that require the visualization of the apparatus, as taught by Conlan et al. (column 10, lines 6-13).

8. Claims 11, 23, 29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komura et al. in view Conlan et al., and further in view of Young (US Patent No. 6,219,572).

As discussed above, Komura et al. in view of Conlan et al. meet the limitations of claim 10, 22, 28 and 35. However, they do not specifically disclose that their method includes the step of providing the marker comprises providing the tip of said in-body penetrating portion with inductor elements or applying a contrast agent to the tip of said in-body penetrating portion. Young discloses a method of imaging a region of a patient using a contrast agent, which comprises the steps of acquiring image information before and after a contrast agent has been injected into the vascular system of the patient (column 1, lines 56-60). They disclose that a liquid free of contrast agent is first injected through a catheter, which has an exapansible balloon tip, in the vicinity of the region being imaged, and then acquiring image information after the liquid has been injected and after the liquid has been replaced with blood containing the contrast agent (column 1, lines 56-64; column 3, lines 3-36). At the time of the invention, it would have been obvious to one of ordinary skill in the art to apply a contrast agent to the tip of said in-body penetrating portion. The motivation for doing so would have been to be able to enhance the view of the tip in imaging procedures, such as MRI, as taught by Young (column 1, lines 9-27).

9. Claims 12, 24, 30, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komura et al..

Komura et al. do not specifically disclose that when a target organ or tissue moves with body motion, a phase image of complex magnetic resonance signals following the movement or covering a range of the movement is captured. However, they do disclose that spatial phase distributions are collected at different times (column 2, lines 41-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art that a phase image following the movement or covering a range of movement is captured in the method of Komura et al. because the target organ or tissue may be moving during the spatial phase distribution collections that occur at different times, and therefore the movement would be captured (column 2, lines 41-49).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER